

Appl. No. 10/078,042
Docket No. 8430L
Amdt. dated September 29, 2009
Reply to Office Action mailed on June 29, 2009
Customer No. 27752

REMARKS

Claim Status

Claims 1-10 and 14-30 are pending in the present application. No additional claims fee is believed to be due.

Claims 11-13 were previously canceled without prejudice.

Claims 1, 6, 8 and 9 are amended herein. Support for the amendments is found in the specification at, *inter alia*, page 3, lines 16-17; page 4, lines 26-28; page 11, lines 5-15; page 14, lines 23-26; page 17, lines 15-27; page 18, lines 1-4 and 17-27; page 19, lines 4-7; page 21, line 1 – page 23, line 19; and Fig. 3 (asthmatic condition); and page 16, lines 5-11 (electronic data analysis mechanism).

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 U.S.C. §101

In Paragraph 3 of the Office Action dated 12/09/08, Claims 9, 10, 14-20, 25-26 and 30 stand rejected under 35 U.S.C. §101 based on the Office's assertion that these method claims do not recite a device which is used for carrying out the method.

Without waiving any arguments they may otherwise have, Applicants have amended independent Claim 9 in a manner which they believe resolves the rejection.

Rejections Under 35 U.S.C. §103(a)

Under MPEP §2142, the Office bears the burden of factually supporting an asserted *prima facie* conclusion of obviousness. In determining the differences between the cited art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1537; 218 U.S.P.Q. 871 (Fed. Cir. 1983). If the Office does not demonstrate *prima facie* unpatentability, then

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without more, the Applicant is entitled to the grant of the patent. *See In re Oetiker*, 977 F.2d 1443, 1445; 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992).

To establish a *prima facie* case of obviousness under 35 U.S.C. §103, the Office must show that all of the claim elements are taught or suggested in the prior art. *See, e.g., CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342; 68 U.S.P.Q.2d 1940 (Fed. Cir. 2003).

Additionally,

a patent [claim] composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727, 1741, 82 U.S.P.Q.2D 1385 (2007).

Accordingly, the Federal Circuit subsequently stated:

[A] flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("[A]s the Supreme Court suggests, a flexible approach to the TSM test prevents hindsight and focuses on evidence before the time of invention."). The TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence—teachings, suggestions (a tellingly broad term), or motivations (an equally broad term)—that arise before the time of invention as the statute requires. As KSR requires, those teachings, suggestions, or motivations need not always be written references but may be found within the knowledge and creativity of ordinarily skilled artisans.

Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1364-1365; 86 U.S.P.Q.2D 1196 (Fed. Cir. 2008) (judgment of nonobviousness and infringement affirmed).

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. . . "[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006); *see also KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 167 L. Ed. 2d 705 (2007) ("To facilitate review, this analysis should be made explicit.") (*citing Kahn*, 441 F.3d at 988). . . .

. . . [K]nowledge of a problem and motivation to solve it are entirely different from motivation to combine particular references to reach the particular claimed method. *Innogenetics*, 2007 U.S. Dist. LEXIS 193, at *17 ("A generalized motivation to develop a method is not the kind of motivation required by the patent laws."). . . .

Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1372-1373, 85 U.S.P.Q.2D 1641 (Fed. Cir. 2008) (affirming district court's rejection of defendant's obviousness defense).

Rejection of Claims 1, 2, 5, 9, 10, 14-20 and 25-30 Over Sheehan in view of Frasca, Jr. in further view of Walker and
in even further view of Filangeri and in even further view of Gilham

In Paragraph 5 of the Office Action, Claims 1, 2, 5, 9, 10 and 14-20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sheehan (USPN 6,319,199) in view of Frasca, Jr. (USPN 6,055,506) in even further view of Walker (USPN 5,828,751) and in even further view of Filangeri (USPN 6,093,146) and in even further view of Gilham (USPN 5,291,400).

In Paragraph 5(D), Claims 25 and 26 stand rejected over the same references.

In Paragraph 5(E), Claims 26-30 stand rejected over the same references and Official Notice.

Applicants respectfully traverse the rejections.

Without conceding the correctness of the rejections in any respect, and without waiving any other arguments they may have, Applicants discuss only particular elements below.

As amended, Claim 1 recites a system to improve the management of an individual's health, the individual suffering from an asthmatic condition, the system including, *inter alia*, a data measurement mechanism generating data relevant to the individual's asthmatic condition; and at least one data analysis mechanism that performs

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at least one analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy comprising collection of the data on a plurality of days. By dependency, Claims 2 and 5 include these elements.

As amended, Claim 9 recites a method for improving the health of an individual, the individual suffering from an asthmatic condition, the method including the steps of, *inter alia*, selecting at least one health parameter appropriate for the individual based on the individual's asthmatic condition; and creating a sampling strategy comprising collection of data on a plurality of days, for measuring at least one health parameter of interest. By dependency, Claims 10, 14-20 and 25-30 include these elements.

With respect to Claims 1 and 9, and the claims that depend from them, the Office concedes that the combination of Sheehan, Frasca, Jr. and Walker does not teach analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy (Office Action, Page 4), or creating a sampling strategy (Office Action, Page 6). The Office contends that these missing elements are taught by Filangeri.

As defined by Applicants, "'sampling strategy' refers to the choice(s) or plan for the frequency and timing and method for data measurement." (Specification, page 12, lines 16-17.) Applicants respectfully submit that Filangeri does not teach a sampling strategy. Rather, as best understood by Applicants, Filangeri only teaches a device that has the capability to collect data samples at a rate (100 samples/second) and store 88 minutes of patient data. There is no mention or suggestion of a sampling strategy involving choice(s) or a plan.

As best understood by Applicants, the combined references do not teach or suggest a system or method involving data relevant to an asthmatic condition.

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

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Rejection of Claims 6, 7 and 23 over Sheehan in view of Frasca, Jr. in view of Walker in view of Filangeri and in even further view of Litt and in even further view of Filangeri

In Paragraph 6 of the Office Action, Claims 6, 7 and 23 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sheehan, in view of Frasca, Jr., in view of Walker, in view of Filangeri, in even further view of Litt (USPN 6,658,287), and in even further view of Gilham. Applicants respectfully traverse the rejection.

Without conceding the correctness of the rejections in any respect, and without waiving any other arguments they may have, Applicants discuss particular elements below.

As amended, Claim 6 recites a system to improve the management of an individual's health, the individual suffering from an asthmatic condition, the system including, *inter alia*, a handheld data measurement mechanism generating data relevant to the individual's asthmatic condition; and at least one data analysis mechanism that performs at least one analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy comprising collection of the data on a plurality of days. By dependency, Claims 7 and 23 include these elements.

The Office concedes that the combination of Sheehan, Frasca, Jr., Walker and Litt does not teach analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy (Office Action, Page 10). The Office contends that these missing elements are taught by Filangeri.

As defined by Applicants, "'sampling strategy' refers to the choice(s) or plan for the frequency and timing and method for data measurement." (Specification, page 12, lines 16-17.) Applicants respectfully submit that Filangeri does not teach a sampling strategy. Rather, as best understood by Applicants, Filangeri only teaches a device that has the capability to collect data samples at a rate (100 samples/second) and store 88 minutes of patient data. There is no mention or suggestion of a sampling strategy involving choice(s) or a plan.

As best understood by Applicants, the combined references do not teach or suggest a system or method involving data relevant to an asthmatic condition.

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For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection of Claims 8 and 24 over Sheehan in view of Frasca, Jr. in view of Walker in view of Filangeri in further view of Falcone and in even further view of Zadrozny and in even further view of Gilham

In Paragraph 7 of the Office Action, Claims 8 and 24 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sheehan, in view of Frasca, Jr., in view of Walker, in view of Filangeri, in further view of Falcone (USPN 5,464,102), and in even further view of Zadrozny (USPN 6,540,674), and in even further view of Gilham. Applicants respectfully traverse the rejection.

Without conceding the correctness of the rejections in any respect, and without waiving any other arguments they may have, Applicants discuss particular elements below.

As amended, Claim 8 recites a system to improve the management of an individual's health, the individual suffering from an asthmatic condition, the system including, *inter alia*, a data measurement mechanism generating data relevant to the individual's asthmatic condition; and at least one data analysis mechanism that performs at least one analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy comprising collection of the data on a plurality of days. By dependency, Claim 24 includes these elements.

The Office concedes that the combination of Sheehan, Frasca, Jr., Walker, Falcone and Zadrozny does not teach analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy (Office Action, Page 13). The Office contends that these missing elements are taught by Filangeri.

As defined by Applicants, "'sampling strategy' refers to the choice(s) or plan for the frequency and timing and method for data measurement." (Specification, page 12, lines 16-17.) Applicants respectfully submit that Filangeri does not teach a sampling strategy. Rather, as best understood by Applicants, Filangeri only teaches a device that has the capability to collect data samples at a rate (100 samples/second) and store 88

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minutes of patient data. There is no mention or suggestion of a sampling strategy involving choice(s) or a plan.

As best understood by Applicants, the combined references do not teach or suggest a system or method involving data relevant to an asthmatic condition.

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

Remaining Statutory Rejections

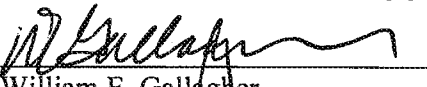
The remaining statutory rejections set forth in the Office Action in Paragraphs 8 and 9 thereof concern only dependent Claims 3 and 4. Claims 3 and 4 are dependent from Claim 1. As set forth above, Applicants submit that Claim 1 is patentable over the art of record. If Claim 1 is patentable, then Claims 3 and 4, being dependent therefrom and narrower in scope, are also patentable. Applicants, therefore, without conceding the correctness of the rejections or waiving any arguments they may have, defer argument concerning Claims 3 and 4 and the rejection set forth in the Office Action at Paragraphs 8 and 9 thereof.

Conclusion

This response represents an earnest effort to place the present application in proper form for allowance. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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